ATTACHMENT

Date	Event
[redacted]	Eagle submits ANDA with FDA.
April 8, 2020	During the April 8, 2020 teleconference with the Court to discuss the Covid-19 related postponement of the scheduled trial, Eagle [redacted] Ex. A (4/8/20 Tr. at 7:21-23, 8:17-19, 9:22-25). On that basis, the Court sets another status conference for May 18. *Id.* at 11:13-16; 22:14-17.
May 18, 2020	Eagle represents to the Court that the [redacted] Ex. B (5/18/20 Tr. at 33:13-34:3, 37:2). The Court orders Eagle to inform it as soon as it hears back from the FDA. *Id.* at 40:3-4.
June 19, 2020	FDA [redacted]. Ex. C at 5.
June 24, 2020	Eagle [redacted] Ex. D.
July 30, 2020	Eagle [redacted] Ex. E (7/30/20 Eagle letter to FDA) attachment at pp. 19-20 of the PDF.
August 28, 2020	The FDA [redacted] Ex. F (8/28/20 FDA letter) at 2 (italics added).
[redacted]	[redacted]

Date	Event
September 24, 2020	Eagle [redacted] Ex. G (9/24/20 [redacted] at 4-8.
September 26, 2020	The FDA [redacted] Ex. H (9/26/20 FDA Acknowledgement).
October 4, 2020	FDA emails Eagle to state that it has a priority review status, [redacted] Ex. I (10/4/20 FDA email).
October 17, 2020	30 Month stay expires.
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	:	CIVIL ACTION
Plaintiffs,	:	
vs.	:	
EAGLE PHARMACEUTICAL INC.,	:	
Defendant.	:	NO. 18-823-CFC

- - -

Wilmington, Delaware
Wednesday, April 8, 2020
2:33 o'clock, p.m.
***Telephone conference

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

- - -

APPEARANCES:

FARNAN LLP
BY: MICHAEL J. FARNAN, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

APPEARANCES (Continued):

DECHERT LLP
BY: ROBERT D. RHOAD, ESQ.
(Princeton, New Jersey)

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DECHERT LLP
BY: MARTIN J. BLACK, ESQ.
(Philadelphia, Pennsylvania)

Counsel for Plaintiffs

POTTER, ANDERSON & CORROON LLP
BY: BINDU A. PALAPURA, ESQ.

-and-

KIRKLAND & ELLIS LLP
BY: JEANNA M. WACKER, ESQ. and
BRYAN HALES, ESQ.
(New York, New York)

Counsel for Defendant

- - -

P R O C E E D I N G S

(The following telephone conference commenced at 2:33 p.m.)

THE COURT: Good afternoon, everyone. So let's begin with the plaintiffs, please.

MR. FARNAN: Good afternoon, Your Honor. It's Michael Farnan for the plaintiff, and with me on the line is Martin Black, Bob Rhoad and Dan Roberts from Dechert.

THE COURT: All right. And then for the defense?

MS. PALAPURA: Good afternoon, Your Honor. Bindu Palapura from Potter Anderson, and with me on the line today is Bryan Hales and Jeanna Wacker from Kirkland & Ellis.

THE COURT: All right.

MR. HALES: Good afternoon, Your Honor.

THE COURT: Good afternoon. And just for the parties, I will let you know, we were contacted, our chambers was this morning by e-mail by -- well it's not clear who, but asking to participate in this call, and I just decided, because I thought it would be very brief and just dealing with scheduling, to just keep it among the parties. I'm not one that generally likes to close off proceedings, but in the normal course, this type of telephone call would not have been a public event, and so that's why I did it in this circumstance.

So we've got a trial scheduled for May 18th and I'm just concerned given the current circumstances of the world that that is not really a doable date.

Do the plaintiffs have any position on this?

MR. BLACK: Yes, Your Honor. It's Martin Black.

My understanding from talking to Mr. Farnan is that there's really no way we could make it work. In addition to the likelihood of some extension to the current situation, there's a law in Delaware that says that anybody who enters Delaware from out of state has to quarantine for two weeks before they can do anything, which would make it impossible for us to go to Delaware and prepare even though I only live a few miles up here in Philadelphia.

We have an expert from California who is working at a hospital right now. I don't know how we could get everybody to Delaware and get them to the courthouse without violating Delaware law and I don't even know whether we would be out of quarantine by the 18th. It seems unlikely. So I think we probably are going to need to make some adjustment.

So Your Honor knows, the 30-month stay in this case expires on October 17th, and somewhat oddly, the defendant does not have tentative approval yet. As I think the Court is probably aware, the FDA grants tentative approval when the application is ready except for the 30-month stay, but they still don't have approval yet, so it may be that this is all a little premature.

The final issue is, we have another trial on these same patents with I think five co-defendants scheduled for January, so one somewhat elegant solution would be to move this trial to next January with the others. We would have to deal with the 30-month stay. If they obtained approval, we could hopefully do it by agreement, but if not, we could do a PI on the papers regardless of the Court's status.

So those are our thoughts. You know, we're trying to be creative. But I don't even see a trial date on May 18th.

THE COURT: Okay. And what do the defendants have to say?

MR. HALES: Thanks, Your Honor. This is Bryan Hales on behalf of Eagle.

So Mr. Black's suggestion to move to January is one that was raised before in the last call we had. We still don't agree to that, so just -- and I know the Court

understands this from our last call, where we were having --

THE COURT: Look, I have no recollection of your last call.

MR. HALES: Fair enough.

THE COURT: It's impossible. If you want to just tell me, I'm happy to --

MR. HALES: Fair enough. Your Honor after our last call had kindly put in a very fast briefing schedule because of the significance of that October expiration of the 30-month stay, and just so you know, from Eagle's perspective, we have two really important competitive interests.

One is that we're a first filer with statutory exclusivity over some of the other proposed ANDA filers, and the other is that for a few where we don't have the statutory exclusivity, frankly, the company just invested time and effort into being the first one to get its ANDA in, and so while we, to be clear, understand the challenges in May, and I will get to that in just a moment, the fact that we have the statutory exclusivity, and for those where we don't have that, we had a May trial as compared to their January trial. Those differences in time are immensely important to the company in terms of its ability to protect its investment that it put into this particular ANDA product.

And so with that said, you know, moving back to January would eat up the statutory exclusivity and the other logistical or the investment-based advantage that we have over those entities.

And so our goal recognizing in these very odd circumstances that it doesn't seem likely that we could have a trial in May given the things that Mr. Black has outlined, our request would be that we try to figure out when -- you know, pick another date that is as soon as we reasonably can that is available for the Court where we think with some blessings that we're in the clear to actually proceed at that time, whether that's later in June or July.

I mean, obviously, nobody has a crystal ball. We don't know when we are going to come out of this, but what we want the Court to understand is that it is really, really important to the client that we try to do whatever we can to try to protect the exclusivity and the time that the company invested an awful lot into.

Oh, and finally -- finally, Your Honor, sorry. On the tentative approval question, there's no guarantee, of course, but our expectation, and we've been in touch with our client on this, is [redacted], so that will play out how it plays out, but there's nothing about that situation that would cause us to agree or agree that a January trial

with the others is a good idea.

THE COURT: All right.

MR. BLACK: Obviously, we'll do whatever makes sense with your calendar, Your Honor. It is odd they don't have approval from the FDA yet, so the urgency is not normally what it is at this stage. We think they filed the application early and incomplete and now they have problems.

We actually -- their stability data that they have been running tests on which they have not produced to us, which they should have, we don't know what's going on and nobody can know when the FDA is going to give an approval or if they will do so.

THE COURT: Well, can I just ask. So to the defendants, do you expect us to go to trial when you didn't have approval?

MR. HALES: Well, Your Honor, our belief is that we were going to have approval in [redacted]. That's the latest understanding that I had the from the client.

THE COURT: Do you recall -- what did you tell me, if you recall, on the last phone call about the expected approval date?

MR. HALES: To be honest, Your Honor, I don't recall it coming up on the last call.

MR. BLACK: I know they've been telling us

forever that they are just about to get approval. Nobody knows. In the normal course you don't know whether you are going to get approval. Now with what's going on, who knows what that group in the FDA is doing and how active they are.

My only point is, Your Honor, if we're going to set a trial and lock something in in July or August or something like that when they don't have approval and then we're going to retry the same patent, the same validity defenses in January with a bunch of other defendants, you know, it's going -- we're going to have to expend an enormous sum trying the case twice, but that's us.

We have commercial issues. They have commercial issues. Your Honor has a scheduling docketing pandemic issue. We will do whatever makes sense from your perspective. One thing we could do is wait until they get tentative approval. If they get it in [redacted], we can regroup and figure out whether we can do a trial at some, you know, some form. We'll, of course, do whatever works for the Court.

MR. HALES: Your Honor, it's Bryan Hales again.

Just the -- [redacted] is the date by which the FDA is supposed to respond to our last submission, which is why we have understood, you know, and our client believes that they are going to have approval. I absolutely -- that

is in the FDA's hands, but that's what we were going on, and just by point of reference, I mean, it does happen that trials happen without, where you're still waiting to get tentative approval and sometimes that comes even between the trial and the decision. I think that's kind of the structure that -- I wasn't involved in the case at the very first scheduling, Your Honor, so I can't comment on that, but --

MR. BLACK: I think he made an important clarification, which is if they're expecting a response on a particular day from the FDA, but the last submission that they made was massive, and they don't know what's going to be in that response.

So when Mr. Hales says he thinks they are going to get approval, their client is hoping to get approval in [redacted] but all they know is that the FDA is likely to respond on a particular day and that response could very well be you've got more work to do.

I don't think it was accurate to represent that they know they're going to get approval. We could revisit if they get approval, but they don't have it yet.

THE COURT: All right. Well, we're going to cancel the trial for May 18th. I just don't see how that's possible, and I think the better course would be to plan on a phone call in May and just to revisit this.

It's going to be very, very difficult. It's very difficult to move stuff, so I'm mindful of the benefits of being the first out there on the market and that's why it looks like we scheduled the trial for when we did, but there are a lot of equities competing here.

So I think what we'll do, we'll take it -- I don't think it would be beneficial -- I don't even know if it's possible to schedule a trial between May and September, for instance, so let's just see.

So [redacted] Is that what you said?

MR. HALES: Correct, Your Honor, yes.

THE COURT: So why don't we have a call -- why don't we just do the call on May 18th, the original first day of trial, and we can hopefully know more then and then revisit this. All right?

MR. HALES: Your Honor, this is Bryan Hales.

Could I have a moment to raise one other proposal in relation to this?

THE COURT: Sure. Yes.

MR. HALES: So back in the early -- the first scheduling conference, one of the things that was raised by defendants was the possibility of filing a motion for summary judgment, which I understand the Court normally doesn't have in bench trial situations. And one of the

reasons that -- you kindly heard us, heard them out, it wasn't me, but heard it out for a couple of minutes, and one of the reasons that that wasn't accepted by the Court as a way to proceed was that the summary judgment motion we were proposing wouldn't resolve the entire case because it didn't cover all six patents that were then at issue.

So at that time Par dropped three of the patents and the same issue of summary judgment would be case dispositive and it's a noninfringement only issue, and in sixty seconds I can tell you why I think it is so compelling.

In light of the situation, our hope was that the Court would consider letting us do that. And the quick story is that all of the three remaining asserted patents have a requirement of a pH level between 3.7 and 3.9 or specifically 3.8, within that range.

Eagle's proposed ANDA requests approval of a drug product with a specified [redacted], outside of the range of all of the claims and Par is only asserting literal infringement. They would have no DOE case.

So if we get approval for that, Eagle is not able to sell anything but a product that has [redacted], and that [redacted]

And the case law is clear that when you have an

ANDA specification that resolves the question of infringement like here, where the claim has something required and the ANDA specification requires something different, the ANDA spec controls I think largely because that's all we would have approval to sell. And so that is one, I think that's -- we believe it's a clean legal issue that would resolve the case and resolve everything that's left in the case at this point.

The only thing that Par has -- the second point to that, the only thing that Par has that they are using to keep this case going forward, and these are two independent grounds to win. If we're right on the law, which I believe we are, the spec controls, it's the end of the case. Par is going to have to argue that it doesn't. And then what they are left with, if the spec doesn't control, the ANDA specification, [redacted] And contrary to what Mr. Black has said, we produced all of our stability data, [redacted], and there's a body of clear Federal Circuit law on this as well that when you have literally one or a small number of anomalous outlier points, that's not enough to carry the burden on infringement.

So those two issues we think are legal issues

that could dispose of the case, and particularly with the circumstances and the uncertainty about when there could be a trial, we request permission to present that motion to Your Honor, again noninfringement only, and those two issues.

THE COURT: What do the plaintiffs have to say?

MR. BLACK: Your Honor, Martin Black for the plaintiff.

So they made [redacted] Some of those tests have been submitted to the FDA. Some of them, we're not sure what has been submitted. We know that they have additional stability data on batches that are right now being tested and they have refused to give us the data for that.

We do not agree with them on the facts therefore. [redacted], and we don't --

THE COURT: Wait. Let me just ask. So, Mr. Hales, let's just address that point first. Does your client have a batch that falls outside the range that it can

sell?

MR. HALES: There's no batch, Your Honor. I believe what Mr. Black is referring to is what I said. [redacted]. That's the anomaly law that we talked about. [redacted]

THE COURT: All right. So how does this work? You said there were multiple measurements done on this one batch. Is that correct?

MR. HALES: Yes, that's correct. That's correct.

THE COURT: All right. How big is that batch?

MR. HALES: I don't know the answer to that, Your Honor. It's something we could obviously find out, but off the top of my head, I don't know the answer. What I do know is that because these products have an initial pH and then they have a shelf life during which these drugs can be administered, their pH is measured at the release point and then certain amounts of them go into stability testing or monitoring and then periodically, you know, one, three, six,

nine, twelve months, a pH read is taken.

[redacted]

THE COURT: So is that --

MR. HALES: Every other test --

THE COURT: Sorry to interrupt.

MR. HALES: Yes. Thank you.

THE COURT: If it has a 24-month shelf life and you did the measurement on the last day of the twenty-fourth month, how do you sell that product at all? Isn't that product gone?

MR. HALES: You can't, correct.

THE COURT: So then why didn't you just at the outset say you would -- okay. So then as a factual matter -- fair enough. I guess it's a little ambiguous.

So this one particular batch, it's done. It's over.

MR. HALES: That's correct.

THE COURT: All right. So, Mr. Black, so why is that an issue?

MR. BLACK: Yes, Your Honor. This is an ANDA case. The product is not on the market, obviously, and what they did is they made three sample batches that they

submitted the data from with their ANDA, hundreds of points.

They look at the -- they look at the status at 1 month, 3 months, 6, 9, 12 up to 24. They need to get 24-month approval, because that's what our product has. If they get a product that's only good for 12 months or 15, it's not going to be saleable.

So they have asked for 24 months. They submitted data to the FDA which indicate that our experts say before the 24 months, I don't know how many months, that specific batch was in the pH range. We now have to say what's going to happen when they make the product and it goes out into the public, and that's evidence of infringement. We'll be selling some product which falls within our spec.

Similarly, under 271(a) --

THE COURT: But what I don't get is, when you say it falls within the spec, if the FDA says they can't put it on the market except as it falls within the range that, as I understand it, does not fall within the range covered by the patent, then how do you have infringement?

MR. BLACK: If the actual product they sell ends up falling within the range over the period of its life, then that's infringement. That's infringement.

They can sell the product at a particular level, but [redacted] when they sell it to 3.7 at any

time over the 24 months, then there's infringement, and we have expert evidence on this. The experts are going to disagree about what is going to happen in the real world and it's not the sort of thing which is ripe for summary judgment.

MR. HALES: So, Your Honor, Bryan Hales again.

If I can just throw two quick thoughts in there and I can name a case.

One thing that Mr. Black says that's true, we don't have a product on the market yet and that's one of the reasons that the Bayer case, which is a Federal Circuit case, says that the ANDA specification controls. Right?

One thing I clearly disagree with Mr. Black on is, if we get approval to market a product at [redacted] we can't sell anything but that. That's what the Bayer case makes clear why that specification that we're seeking approval controls the question of infringement.

The second point, because the product isn't sold yet, clearly, we can't sell the batch that has the 3.8. It's way past its life, so Mr. Black is wrong about that. But these anomaly cases, this anomaly line of cases exists in this context because what Par has to try to say is that there's some theoretical expectation that our pH is going to, against the specification and against the process controls [redacted] into the claimed

range, the approved amount of [redacted] into the claimed range of 3.7 to 3.9. And the only thing that anybody has to go on is the set of data.

THE COURT: Right.

MR. HALES: And so one point is an anomaly. Sorry, Your Honor.

THE COURT: All right. Hold on.

So, Mr. Black, do you agree with that, that that is kind of the nub of the dispute?

MR. BLACK: I think that's the nub of the dispute and the experts disagree with whether if they sell something at [redacted]

All they have to do is move [redacted] and we have an actual example.

THE COURT: All right. Just let me stop you. Sorry. Mr. Hales --

MR. HALES: Yes.

THE COURT: -- if you stipulate for purposes of summary judgment that the product could over time -- I mean, see, if it's a dispute among experts, then we don't have summary judgment. But if you are telling me --

MR. HALES: Sorry, Your Honor.

THE COURT: No, no. I'm just trying to, and

I've got to wrap this up because I've got to move on. But, you know, are you willing to stipulate to what his expert says?

MR. HALES: Not that it's expected it's going to [redacted] because of the anomaly line of cases. Clearly, we would accept, we accept that there is [redacted]

What the Federal Circuit cases say, like there's a case called Ferring versus Watson Labs, say that in the ANDA context, when you are looking at whether the patent owner can carry the burden of establishing that it's more likely than not that something like that will happen again, it is not enough to have an anomalous data point. And there are cases where there are for or five data points out of a hundred and they say you can't carry your burden on infringement as a matter of law when you've got a small number of data points.

And what we're saying is out of all of the tests that we've done on all of the batches that we've done over all of the time periods, [redacted] and they can't carry the burden on that as a

matter of law.

MR. BLACK: [redacted]

Our expert said that there's infringement and that if they make this product the way they are planning to make it, there's a lot of detail about how they're making it, it is more likely than not that product will be on the market [redacted] and they will have snuck through.

They will not accept our expert's testimony for the purposes of the summary judgment motion. You just heard them say that. So I don't see how they can get summary judgment. If they are going to dispute our expert's, qualified expert's opinion as to the facts, we're going to have to have a trial.

MR. HALES: Well, with respect, Your Honor, I think Mr. Black is wrong on some of the data. [redacted] y, and a variety of --

MR. BLACK: Have you given us the data on all of those batches up through today, because based on our

information, [redacted]

MR. HALES: Well, my understanding --

MS. WACKER: This is Jeanna Wacker.

We have produced all data that we have to date. The test dates for the other batches is not coming up until next week, so we don't have any of that.

And one other point, Your Honor, I think we need to make is that Eagle is not allowed by the FDA to sell a product [redacted] If that were to occur, the products could be recalled. Eagle could be subject to fines. So we're not legally allowed to sell a product that goes outside of our approved specification.

THE COURT: All right. Well, I'm not going to make a decision on this today, but I may revisit it May 18th. So we will have a call on May 18th at 1:00 o'clock. All right?

MR. BLACK: One last thing. The pretrial order, are those dates suspended for submission of the pretrial order?

MR. HALES: Your Honor --

THE COURT: Go ahead.

MR. HALES: I would say we'd like to keep things moving towards trial ready, so from Eagle's perspective, we would like to keep moving on the pretrial order. We could

make some modest adjustments clearly that we aren't going to be going in May, but we would like to move towards trial ready.

THE COURT: Actually, you know what I'm going to do, I'm going to keep the pretrial dates. So the only thing I'm postponing right now is the trial. I'm keeping all other dates. All right?

MR. BLACK: Okay. Thank you, Your Honor.

THE COURT: I think it will help narrow the disputes and will make a more productive call on May 18th.

All right. Thanks, everybody. Have a good day.

MR. BLACK: Thank you, Your Honor.

(Counsel respond, "Thank you, Your Honor.")

(Telephone conference concluded at 3:03 p.m.)

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EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	:	CIVIL ACTION
Plaintiffs,	:	
vs.	:	
EAGLE PHARMACEUTICAL INC.,	:	
Defendant.	:	NO. 18-823-CFC

- - -

Wilmington, Delaware
Monday, May 18, 2020
1:00 o'clock, p.m.
***Telephone conference

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

- - -

APPEARANCES:

FARNAN LLP
BY: BRIAN E. FARNAN, ESQ.

-and-

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(New York, New York)

Counsel for Defendant

- - -

P R O C E E D I N G S

(The following telephone conference was held beginning at 1:00 p.m.)

THE COURT: All right. Good afternoon. Let's hear from plaintiffs, please.

MR. FARNAN: Good afternoon, Your Honor. Brian Farnan on behalf of the plaintiff, and with me is Martin Black, Robert Rhoad and Brian Goldberg, all from Dechert. We also have Lawrence Brown from Par on the phone.

THE COURT: All right. Thank you. And then let's hear from Eagle.

MS. PALAPURA: Good afternoon, Your Honor. Bindu Palapu from Potter Anderson on behalf of defendant Eagle. With me today from Potter Anderson is my colleague, David Moore. Also with me today is Bryan Hales and Jeanna Wacker from Kirkland & Ellis.

THE COURT: Okay. Great.

All right. Thank you, all. I've read the papers as far as the request for summary judgment.

Let me just ask Eagle a question. Can Eagle sell the product, its ANDA product, if the pH is measured at some point during the shelf life of the product to fall within the range covered by the patent?

MR. HALES: Hello, your Honor. This is Bryan Hales from Kirkland, and let me take that.

The answer to that is, no, we can't sell something that's not in compliance with our specification. All right. We've only sought approval for something that is within the spec on release and through stability. So if we learned of that during the shelf life, then I think the answer to that is no, because we wouldn't have approval for that.

THE COURT: Okay. Because you said in a hearing -- I went back and looked at the transcript. You said they couldn't sell it. But what I guess I'm confused by is, you know, Par has put in the record the regs, and it looks like to me that you could sell it if it didn't -- or you could seek an exception and you could continue to sell it.

MR. HALES: I think the regs -- well, I am not an FDA regulatory expert, Your Honor, but what I think that's contemplating, and when you have a field action is when you learn about something that was in the field. Right? And let's say it's already out there and then you learn something has gone wrong.

THE COURT: Right.

MR. HALES: It seems to me a different scenario.

THE COURT: Well, when you say scenario, that's

what I'm trying to figure out, is it seems to me that this is really what the whole issue turns on, is if you fail to meet the stability spec because the pH level is within the range but you can then go ahead and sell it seeking an exception to, under these field reports, it just strikes me that it's not enough then to say that just because you failed to meet the spec, that you're not going to infringe, that you are not going to have a product out there.

MR. HALES: I guess the response is, what I think I was trying to say is, if we learned about it before the product was sold, then we wouldn't have authorization to sell it, right, because we have not sought approval for that, and the idea that we would try to get an exception to change it I think is speculative. There's no evidence that that would happen.

The field report issues come up when something unexpected happens that was already in the field, and in those scenarios if all you were concerned about is patient safety, let's say there was no patent litigation issue, then it might be that somebody says, we learned something different than expected or different than was approved in the field, that's already out there, and they investigated this as standard stuff for generics, they would investigate, FDA or anybody approved, they would investigate it, why did it happen, and is there a patient safety issue and take

action.

Here you would have a scenario where clearly there would be -- and, again, this is speculating on things that haven't happened, but there would be legal input as well because the ramifications on patient safety are one thing and the ramifications in terms of what Par might allege are a different thing.

So I just think it's too speculative to suggest that we shouldn't have this issue considered now because of those things that might happen, because all of that theory rests, Your Honor, on the premise that Eagle is not going to comply with its spec, and the Federal Circuit cases say that when we're in the ANDA setting, which is where we are, we have no commercial product on the market, Par can't presume that there's going to be noncompliance with the spec.

THE COURT: No, but there's a difference, it seems to me, between the cases. I mean, I actually don't think you -- well, I don't think you have fairly summarized the cases in their totality. I think you have taken language out of the Elan case and then you've ignored essentially the holdings of the subsequent cases.

So, yes, I think the Federal Circuit has clearly said we're going to presume that there's compliance with the ANDA, but they've said you can look to extrinsic factors,

and they took comfort in Elan because there was no suggestion by anybody that the ANDA wasn't going to be complied with and would not lead to sales. The difference is you've gotten -- and then in the other cases where they've got a product on the market, it's a different question.

That is what we have here, is we've got a product that, it seems to me there's a factual dispute, we can get to that in a second, over whether or not the stability -- [redacted], and you are asking me to take comfort in the fact that, yes, but we're not going to sell it if we know about that. But this is not something that every day before the product is sold there's a test run. And so as I understand it, there's some kind of, I don't know if it's random or some periodic testing, and if that testing reveals that you've got product that does not comport with the spec, you're still not precluded necessarily, as I understand it, from selling the product. You would have to at that point get into some kind of safety determination.

I mean, is that not a fair summary, at least the last part, that it is not a mandated removal from the market, but instead there would be some kind of safety considerations to determine whether or not the product could

be continued to be sold?

MR. HALES: Well, again, I have to say, Your Honor, I'm not a regulatory expert to be sure, but I do think again there's a difference. Right?

We are seeking approval, Eagle is seeking approval to sell a product that has a pH spec on release and maintained through shelf life, so if we learned that it was not maintaining before it went out the door, I don't think we could sell that, because we don't have approval to sell that.

THE COURT: And I think if you could guarantee me that the thing never got -- never got to the market, that's one thing, but I don't think you can do that, it sounds.

MR. HALES: Well, I think this is the point of the cases that say we don't make those presumptions though. I mean, I can't sit here today, but if we disagree with Par's assertion that there's going to be this [redacted] all right, clearly, but we're on summary judgment, so I understand the context.

I can't guarantee in the context of summary judgment for sure that that hypothesis would never happen, but I think we are being fair about the cases, because if you look at the In re Brimonidine case, it's a very, very analogous situation to this one where the claims required a

pH above seven. The ANDA specification required 6.5 to 6.7. The parties in that case agreed that pH would drift down over time, and so the plaintiff hypothesized that in order to never go below 6.5 during shelf life, which is what the ANDA spec said, the product would have to begin above .7, which would be out of spec and within the claims and therefore there was infringement.

And the Federal Circuit said, no, we cannot make that presumption that they're going to release out of spec.

The --

THE COURT: But I mean let me just -- sorry to interrupt. I mean, isn't release a different story, because there the FDA is involved and you are not worried about there being a sale, I mean, as opposed to something that is passive. In other words, when you are doing the release, right, your client is actively making the product, has to ensure compliance before it leaves the factory, but once you put it on the shelf, there's not that kind of active insurance that if, in fact, the [redacted], it's not going to be sold and sold as an infringing product.

MR. HALES: But I think that's the same as Brimonidine, because the argument in Brimonidine is that in order for it to stay in spec throughout its life, it would necessarily have to begin out of spec in an infringing

scenario. And the Federal Circuit said you can't make that presumption, and the District Court said, you know, actually found infringement, and the Federal Circuit said, no, you can't make that presumption.

What Par is doing is the same. They are accepting for this purpose that we're releasing the spec, but then they are presuming [redacted] That would be contrary to what we sought approval for. The FDA is not going to give us approval unless they are satisfied that they've got data that shows we're going to maintain our spec, which is a release and stability through shelf life specification.

THE COURT: I think the difference though is that, I don't think there's any question that you can't release if you're in spec. You just can't do it, whereas if you're on the shelf life and you have to issue one of these field alerts, you may actually get to keep your product out there.

MR. HALES: Yes. I guess the response to that is I can't talk to the future and the FDA nuances. Clearly, in that scenario, there would be a legal assessment of this as well, but I think the premise of this whole theory, Your Honor, is that we're not going to comply with our specification, and that's what the cases I think say you can't do.

I think --

THE COURT: I hear you, but I mean at the end of the day, right, I mean, really, you're going to bind your client to say that if its product ends up on the market and there's a random test to determine that, in fact, there's at least one, I don't know if it comes in a bottle or what, but, you know, some vial of this product sitting on the shelf at 23 months and it has got a pH level that infringes, you're telling me -- [redacted] I mean, you are telling me and going to bind Eagle going forward that it has got to take every single vial off the market at that point?

MR. HALES: Well, I guess the point would be, Your Honor, if that were to happen, certainly, there would be an investigation done because we have stability products on the shelf that we test for each batch periodically over time to look for those things, and they would have to figure out is that a one bottle, was it damaged, is it an anomaly or is it representative?

In a scenario where it's representative, I mean, they have to get with us and figure out whether it's representative or an anomaly and the like. And, by the way, what the case law says is at that point, Par has a 271(a) claim, right, and there's product on the market that's not in compliance, so they can sue us at that point.

But I mean that to me is the, one of the important differences about the law. The cases say you can't presume noncompliance with the ANDA spec when you are not yet on the market, and if there is a -- something goes out of spec when it's commercial, then there's a 271(a) case to be filed. That's exactly what happened in the Barr/Elan -- sorry, Bayer/Elan, which we cited, and Bayer/Biovail, which Par has cited.

If you look at the 30-milligram example in the Elan case that we cited, it is a milligram dose. The argument was made in the initial case that the spec was -- didn't allow infringement. There was a finding of noninfringement affirmed by the Federal Circuit and the argument was made that you should be looking to batch data and the like or other data that would suggest that they weren't going to be able to comply with the spec or there was going to be some out-of-spec activity, and the Court said no. And then in the subsequent case on the 30-milligram dose, there was a commercial product on the market that they argued without a spec and there was a 271(a) claim.

So here I think their point is that their theory, [redacted], which obviously is the theory itself and on the merits we'll dispute at a later date, but [redacted], there's no room for that in a situation

where there is not commercial product on the market and you just have an ANDA spec where we're asking for approval of something that can't infringe with compliance.

THE COURT: But they've brought an action under 271(a) through (c) and they've asked for declaratory relief. I mean, why doesn't that alone cover it? If you put aside -- I think you can almost put aside Waxman.

If you know somebody is on the verge of letting a product go and you've got evidence that over the course of its shelf life it's going to infringe, why can't you just bring a regular old patent action at that point, and haven't they really done that?

MR. HALES: I don't think that's a viable claim and that could literally be a very short section of the end of our SJ motion. It would be. There's no -- we have no commercial product on the market and all of the activity that we've done is exempt from infringement. Right? So they can't state a 271(a) claim right now.

THE COURT: All right. Let me hear from the plaintiff.

MR. BLACK: Thank you, Your Honor. Martin Black.

I think Your Honor has accurately assessed the cases. The first case that they cited, Elan, was an early case, and the follow-on case is particularly Tyco

Healthcare, and even interestingly another case in that same line with Elan says that the ANDA gives you a starting point, but if there's evidence in the record to suggest that the ANDA doesn't tell the whole story, then that can create an issue of fact. And in the type of case in particular, the Court said we found it significant in Elan, the case they rely on, that the patent owner did not allege that the generic manufacturer's commercial product would infringe in spite of the ANDA spec. We've made that allegation and we've backed it up with evidence and this is summary judgment.

Ironically, in the second round of the Bayer litigation, there was a 60-milligram ANDA which they keep ignoring. There was a 60-milligram ANDA. Because by the time that ANDA was challenged, there was additional evidence available, the Court said, fine. We can have a different view about what happens with the 60s and the 30s.

So we're here on summary judgment. The law says you rely on the ANDA and all available evidence to predict what will happen in the future, and, by the way, you do the same thing with respect to a 271(a) claim, which is not bound by any of the -- even if you accept their view of the law in Hatch-Waxman, you are correct, it wouldn't bind on 271(a), which is just a straight-up base. They're ready to go to market. [redacted]

[redacted] They want to go, and we say if they do, they're going to infringe. We bring all evidence to bear. We have an expert opinion and that should be sufficient.

Now, the one thing that I want to amplify is that the claims at issue in the case are method claims for administering a drug with a unit dosage form with a pH of 3.7, 3.8, 3.9, and just because they release the product on a particular day [redacted]

But, most importantly, this is summary judgment. There are lots of, at a minimum, fact issues. If anything, we believe we would be entitled to summary judgment, but certainly, this is not a good candidate for an expedited summary judgment process or to go around the rule as we usually have in ANDA cases, you have no summary judgment. But I will point out that we got here based on three representations that were made at the last hearing, which were not completely accurate.

The first was a procedural representation that we had to do this because [redacted]

[redacted]

The second was a representation about the law that all you do is look at the ANDA, which Your Honor observed is not the law.

And the third is that the result we're relying on is an anomaly, and it is clearly not an anomaly based on the evidence, and in any case, if that evidence is disputed, can form no basis for summary judgment.

Thank you.

THE COURT: All right. Let me just ask one --

MR. BLACK: Your Honor.

THE COURT: Yes. Hold on. Mr. Black, let me just ask you one question. You know, you talked about that you could show that at some point during the distribution chain, the product could be infringing. You know, what do you have to prove to show that it could be? That does seem speculative.

MR. BLACK: No, it's not speculative, Your Honor. It's a question of what you have to prove in a Hatch-Waxman case before the product is on the market.

We have to show that there's a reasonable likelihood that they'll infringe and [redacted]

[redacted]

So we know that if they sell within their spec, it's [redacted], [redacted]

Now, they could remove the problem by [redacted] n which case there would be no proof available that the product would ever [redacted], in all likelihood. But they decided not to do that, and that's important here, because they understood that they had a batch they made, one of their three batches for the FDA process. They made it at [redacted]. They could have dealt with the problem, but they decided not to, and they're continuing to try to get approval of that ANDA.

So as long as they reserve the right to sell at [redacted] which they do and which we had to assume they can do under the Sunovion case, they are taking -- they are selling a product which we know is going to ultimately fall into our range.

THE COURT: All right. Okay. And I mean another way I guess of just kind of responding to my question is essentially, right, I mean, Hatch-Waxman, it is all about an injunction. That's why reasonable likelihood

is a standard.

MR. BLACK: Right.

THE COURT: That's why it could infringe is really the operative question.

MR. BLACK: That's right, Your Honor.

THE COURT: Okay. I had to figure that out in my own brain.

All right. Let me hear. Eagle wanted to respond.

MR. HALES: Yes. Thanks, Your Honor. And just to be clear, I mean, Mr. Black is suggesting that these things are definitive and, again, these are for another day, but just to note, we disagree with this theory.

THE COURT: I understand. I get that. You don't have to repeat that. I understand that fully.

MR. HALES: What they've done is wholly speculative. There's no data that behaves the way they are suggesting. So they've got a -- they've looked at some data. They've suggested that there is a [redacted], and then they're applying it to a different set of batches. Right?

So --

THE COURT: I hear you, but at the end of the day, those are facts, right, I mean, that you will have your experts testify and very differently about this and then I

guess I will have to decide.

MR. HALES: I agree on the point that they're trying to raise a dispute, Your Honor, but this is I think why the cases say what they say in terms of the specifications.

One of the things that Mr. Black said was that [redacted], and we didn't put this in the summary judgment motion because that would have probably raised a bunch of fact disputes that are not germane to the ANDA specification control of line of case law.

Our point is that the FDA has our data. They have our specification, [redacted] We've given them the data and more data than Mr. Black is talking about, and they also are aware of [redacted] And the FDA's job is to evaluate whether they are confident that we can meet our requested specification, and if they approve it, then they believe that we can, and our goal is, of course, to design a product that meets it.

And that's why I think the line of cases that are out there are so clear that when the specification

resolved the question of infringement, when you don't have commercial product on the market, the ANDA specification controls.

And we are --

THE COURT: But how do you square that, how do you square that statement with Tyco? I mean, in Tyco the Court held, "It is not unreasonable for a patent owner to allege infringement under Section 271(E)(2)(a) if the patent owner has evidence that the as marketed commercial ANDA product will infringe even though the hypothetical product specified in the ANDA could not infringe," unquote?

You can say it rises and falls with the specification. I agree there's language in Elan that says that, but I think it's under very, very, you know, limited facts that aren't here.

So tell me, how do you distinguish what I just read from Tyco healthcare?

MR. HALES: I mean, the Tyco Healthcare is actually a Noerr-Pennington case. I would take it the reverse. I understand the language here. Number one, the difference is we do not have any commercial product on the market that suggest any contrary behavior to the specification, so that's a difference. It doesn't assist now.

And, again --

THE COURT: Well, now you are back to facts, but I'm commenting on your statement, your opening statement that this rises and falls with the specification.

MR. HALES: Yes. The cases that have actually been -- Tyco is a Noerr-Pennington case on whether it was sham litigation or not. The cases that really confront the issue of are we going -- when there's no commercial product on the market, are we going to look at the ANDA specification or beyond it when the specification controls our cases like Bayer and Brimonidine, which are directly on point? So that to me I think squares it.

And Sunovion, the ANDA specification range overlapped the claimed range, so that's a totally different scenario. This is a scenario where what we're asking the FDA to approve is something that has no overlap with the claimed range, and if they approve it, we have demonstrated to them to their satisfaction that we're going to be able to make that product, and that's on us to demonstrate and it's on them to review.

And that is why I think these cases --

THE COURT: Do you --

MR. HALES: Sorry.

THE COURT: No. Go ahead. Do you dispute that their expert is going to say there is overlap?

MR. HALES: Their whole theory, all they've

presented, and, number one, there's no dispute there's not a commercial product out there. Their expert's theory is that [redacted] if it's for a product that is released at [redacted] into the patented range, the claimed range. That necessarily presumes noncompliance with our specification. That's their main point.

THE COURT: But just to be clear, I just want to make sure. I mean, you do admit, right, their expert is saying something that overlapped? In other words, there is overlap according to their expert? You just don't believe their expert?

MR. HALES: No, no, no. Their expert is making the statement that [redacted] into the claimed range. That is true.

THE COURT: Okay.

MR. HALES: We disagree with that, but that's what they are saying. My point is that his theory, accepting his theory presumes and requires presuming that we will not comply with our ANDA specification, and that's what the law says the District Court and the parties should not be presuming.

THE COURT: But the only thing you are presuming is the stability specifications will not be complied with. Correct?

MR. HALES: Well, we have to comply with all of them. Your point --

THE COURT: I know that. I just want to make sure I understand. Their expert, the presumption that you are identifying that their expert makes is a presumption that you will not comply with the [redacted] requirements. Is that correct?

MR. HALES: Correct. I think he is accepting that we will comply with our [redacted] requirements.

THE COURT: Right. I just want to make sure.

MR. HALES: And what's interesting and the point I wanted to make and I didn't before, Your Honor, but their letter is completely silent on the [redacted] requirement. But that's part of our ANDA, is the [redacted] --

THE COURT: No, no. Actually, I don't think they are. I mean, maybe I teased it out more than they expressed, but I understood them to be -- that is why they cited these field alerts.

Maybe, Mr. Black, do you want to speak to that?

MR. BLACK: You're absolutely right, Your Honor. Put the Hatch-Waxman stuff aside for a moment. Just imagine that we're a regular old patent case. They're threatening a launch of products which they say they're going to sell at [redacted] Our expert comes in. He says, hey, [redacted]

[redacted]

We win at that point. They can't come in and say, oh, the FDA thinks we're going to be okay based on data we provided during the ANDA and we've got an expert who says that data, the FDA didn't even review it completely. They didn't review an infringement question, and our expert says, [redacted] We would have to have a trial over that.

Maybe the FDA's implicit view is somehow the evidence, or actually I doubt it. But we have a dispute of the experts here at best about whether the product is sold at [redacted] There's no way they can get summary judgment.

And the continued misrepresentation that the case law binds in some fashion, it flies in the face of the wording of Tyco and it's just inconsistent. We have to deal with reality in Hatch-Waxman just like anything else. We have an expert report that says [redacted] and that's sufficient to get over the limited bar for summary judgment.

THE COURT: Okay. So I'm going to deny the application to file for summary judgment. I think although there's language in the Elan decision, I think the subsequent cases make clear, and I think, frankly, I think

the language of Tyco Healthcare requires that I deny summary judgment and that this turns and falls solely on the language in the specification.

And I think as far as the anomaly argument, I mean, that's a classic factual dispute that we'll hear from the experts at trial and I will make a decision.

All right. So that application is denied. So now we're on -- what's next? Let's hear from plaintiffs.

MR. BLACK: Thank you, Your Honor. So we have a 30-month stay that expires in October. We have no tentative --

THE COURT: Wait. Hold on. I guess I failed to appreciate that. The stay that's involved in this case is going to expire in October coming up?

MR. BLACK: That's correct, Your Honor.

THE COURT: Okay.

MR. BLACK: They do not have -- and on the last call, which was a call primarily for the scheduling problem that we couldn't have a trial on May 18th, they offered the solution of having a summary judgment process, so we had an impromptu summary judgment argument where we were -- you know, did what we could. Now we've gone through that process, the application is denied.

And they also represented that they were --

THE COURT: Mr. Black, Mr. Black, just so you

know, you got cut off.

MR. BLACK: Oh. I'm sorry, Your Honor.

THE COURT: I'm not sure it was really worth making the point. If you want to rehash that they made a summary judgment application, they did, and --

MR. BLACK: No, no, no. I was just saying how we got here. We had a conference to talk about the schedule.

THE COURT: Right. All right. So what about next steps? We don't have much time.

MR. BLACK: Right. So I think they don't have tentative approval. [redacted]. That could be a thumbs up, thumbs down, or anything in between, and so we don't know where we are, but we don't have an approved product yet. So my suggestion would be that we reconvene [redacted], and we do have a trial set in the companion cases for January.

Now, we could roll this case into that one and do them all together. If they get tentative approval, we can negotiate an extension to the stay, or if we have to, we can come back to Your Honor and ask for relief, but I'm not sure what else we can do at this point.

THE COURT: All right. Let me hear from the

defense.

MR. HALES: Yes, Your Honor. Bryan Hales. Thank you.

So the FDA, we believe it's Covid related. [redacted]

But just to reiterate our points from the last call, the October trial date that we had before the Covid situation was very important to our client because [redacted]

And so I know obviously things got taken away from us through no fault of anybody in terms of the virus situation, but we are very interested in getting to a trial in some fashion, and I don't know what the Court is thinking in terms of Zoom or live trials from a timing standpoint, but it is not -- we're definitely not -- we would hope very much not to be waiting for a January trial and have some way to have a trial ahead of that.

The parties have our pretrial submissions done, and on the last call Your Honor asked us to proceed with those, which we were in favor of, and so those are ready. We just need to understand what options we have to have a

trial so that we don't lose, if at all possible, all of the blood, sweat and investment that the client put in to having this, having this time advantage against the other generics that are waiting to come on some time after a January trial date.

THE COURT: Okay. When can you go to trial?

MR. HALES: Well, we're --

THE COURT: Let's assume for right now that we're doing in-person trials starting June 15th. When can you go to trial?

MR. HALES: Well, as soon as June 15th after we're available, I think we'll be ready. I have not talked to an expert or anybody in particular. We will move heaven and earth to go when the Court could give us, when Your Honor could give us a trial date.

MR. BLACK: Your Honor, we have not talked to our experts to figure out who can travel. We've got doctors and other things in the case.

We had originally, I think when we were on the phone the last time, Your Honor said that the trial would be not before September or October, which is why we had suggested combining this with the next case. They get there 180 days of exclusivity as the first filer.

THE COURT: So help me understand that, because I mean I don't see how it would really work to do a trial

between now and September, which is why I said it. I've got to admit, I think when I said it, I may not have realized there was an October end date for the stay. Maybe I did.

MR. BLACK: Yes. We had discussed it, Your Honor. The client pointed out they didn't have tentative approval, so perhaps it wasn't as urgent as it sounded and Your Honor wondered why we would have a trial without tentative approval. [redacted] And so I think we're still in a position where they don't have an approved product. [redacted]

THE COURT: So let's just spell this out. I mean, I want to do justice to both sides, but, you know, I also -- your summary of my reaction I'm sure is accurate to the extent it was why am I having a trial on an unapproved product. That's for sure.

MR. BLACK: The -- sorry.

THE COURT: No. I'm just trying to figure out, you know, trying to be fair to both sides, what works here. I mean, I've got two cases that are going to trial in September and they are retrials. Rather, one is a retrial. It is definitely going to trial. The following week it's a

very significant pharmaceutical case and it's going to trial. Those are jury cases. And then I've got six Markmans in September, and so I just don't see how we're going to go to trial in September in this case.

You know, you mentioned they've got the 180 days. They lose that, though, right, if we go to trial in January. No?

MR. BLACK: No, no. They get -- they keep their 180 days. It doesn't matter when we go to trial. They have priority over anybody else on the same dosage strength. We filed a similar application.

THE COURT: Okay.

MR. HALES: Your Honor, this is Bryan Hales. If I can respond to that?

THE COURT: Yes, please.

MR. HALES: He's being very careful about the way he words that. One of the defendants in that other case, American Regent, we do not have exclusivity against, so the advantage that we have against them, the competitive advantage is the one that we invested in to have a time advantage based on being ahead of them, but if we are with them at trial, they are coming on at the same time that we come on. There's no 180-day exclusivity for them.

MR. BLACK: They're actually -- well, we just settled with them and they have approval, so there's no --

we may need to flesh this out in a letter or something, Your Honor. It's a little complicated, but there's no -- there's no prejudice to them. They get a 180-day jump on the other defendants if they prevail because they are the first filer. There's this --

THE COURT: Well, wait. You are saying they are going to get a 180-day jump on the party that you just settled with that Mr. Hales pointed out as the same --

MR. BLACK: No, I'm not saying that. I must be careful not to disclose any terms of the settlement on the call.

THE COURT: Okay.

MR. BLACK: But it's not -- it's not a -- I need to back up a step, Your Honor, if you will.

So they filed on one dosage strength, Eagle did, and there's another dosage strength that Sandoz filed on.

On the dosage strength that Eagle filed on when they would have the right to the 180 days, all of the other defendants are behind them stacked up except Eagle filed a different kind of -- excuse me. American Regent filed a different type of filing, so they were never behind Eagle and never will be behind Eagle. So the investment that he's talking about, I don't know what that means. They use different regulatory paths.

That case is now settled though, and I don't want to disclose the terms on the call here, but the argument that they won't get their -- they won't get what they would be entitled to, 180 days, is not correct.

THE COURT: Okay. Well, I mean, I'm just trying to get some kind of comfort level about what the right answer is here because it affects trying to set a trial date.

MR. BLACK: So --

THE COURT: Now, I've heard from other judges, which is just, you know what, the parties can do what the parties want. I mean, we can only do so much here schedulingwise, and so, you know, I guess to that extent, the burden is really on Eagle to explain what it wants and why we can't just do this in January, and you should somehow -- I mean, is there no recourse to compensate for this first filing privilege you have?

MR. HALES: Well, I don't understand what the parameters are of the settlement that Mr. Black is talking about because I've just heard of it, so I can't comment on it. Certainly, we did invest in getting our ANDA filed and the trial date that we had before Coronavirus to get ahead of the other players however they filed, and that's what we've been trying to protect.

We want to make sure that we're ahead of -- even

as to a, like, a Sandoz with a different dose, you know, we still had a competitive posture that was favorable to us because we were just earlier than them, whatever dose that they come on with, because different doses come out of the generics and people will take them up.

So we're trying to protect that even with American Regent gone. Again, I would have to see that agreement to understand nuances and the appropriate parts of it, but that's still important to us and I think it still has value. We can provide more on that maybe after we've had a chance to understand what it is that Mr. Black is trying to convey.

As to the approval point, I just want to make one point clear on the tentative approval issue. Trials happen, and they happen in Delaware sometimes after tentative approval was had and sometimes before. That's kind of the ANDA framework. Right? The case gets filed when we filed the ANDA. And the ANDAs proceed towards -- you know, the generic filer needs to have two things to get on the market. They need to have approval and they need to have cleared the Paragraph 4 litigation pathway. And both of those things have to happen preferably, or you want them to happen before the stay, if you can.

[redacted]

[redacted]

I don't know -- Your Honor, I don't know if the Court is contemplating Zoom trials or anything like that that would allow us to advance, especially in a non-jury scenario. Right? Advance --

THE COURT: Well, I'm definitely not contemplating Zoom because my understanding from the folks in the judicial branch is it's not working that great. We have used the Cisco system, but it's difficult. I had one hearing. Granted, it was a criminal matter and it involved a translator, so it exacerbated the difficulties, but it's just not a very good -- it is very I don't think conducive to, you know, making credibility determinations in a way you normally would with a live witness.

MR. BLACK: Your Honor, here's the issue. If they don't get a tentative approval [redacted]

[redacted]. Unlike Mr. Hales, willing to say over and over again that they have been saying to us for 18 months, we're getting approval tomorrow as they try and negotiate and tell various judges, you know, what's going to happen. [redacted]

And so then we'd be doing a trial in October on the same patent for Eagle coming back for another trial in January on the same patent, enormous expense, eating into Court time.

And the reason we set the trial date for May 18th was also because of both the 30-month stay, and we wanted to give the Court enough time to make a decision, but also we expected they would have approval by now, and they don't. [redacted]

But the bottom line is, as a practical matter, they don't have an approved product and we ought to wait and see if they get one. If they get one [redacted] he's right. We put the pretrial order in. We can figure out when to have a trial. We can be creative, but if they don't, then it seems like we are trying to move heaven and earth for no reason.

MR. HALES: Your Honor, if I can just add, I think Mr. Black has gotten quite a bit ahead of this on his suggestion as to why we do or don't -- why we don't have approval yet, but just from a timing perspective, I would agree that [redacted]

But the one concern we have is we don't have the same exact patent as the case in January, so there's not going to be a different -- a total overlap. We're just trying, our client -- and, again, I'm not the FDA either, [redacted]

[redacted]

And if we -- if we get that and then haven't got a trial in place at a reasonable time, then even if we get it around that time, then we're going to be in front of the Court potentially on some type of expedited relief. Like if we have a [redacted] but we have no trial scheduled because ours -- we don't have a trial scheduled, then we are going to be in a TRO/PI situation. I mean, these things are potentially going to come to a head around that time anyway.

So we're just -- and, again, we're in an unusual circumstance with the ability to do trials, but with a bench trial, our hope is that we can put something down as a place to try the case and then it's in there, [redacted] then we can address that situation and it's easier to remove a date than put one in, I think.

THE COURT: Yes. Actually, this is a fair assumption under normal times, but we're not in normal times. And, you know, here's what my inclination is. I'm not going to be adding a lot of trials, if any, to my

calendar between now and January, and as the normal course goes, and I am hopeful that this normal course will continue is cases settle, so my calendar should free up. And so what I think the better course right now to do is, let's wait. Let's see what happens [redacted]

Is it [redacted] Is that the right date, I believe? Right?

MR. BLACK: Yes, Your Honor.

MR. HALES: [redacted]

THE COURT: The [redacted]

[redacted]

The one thing I would say to both sides is, be prepared to go. So, you know, that's what I would say. You should be prepared to try this case September, October, November next year -- of this year rather, and we'll try to squeeze it in if we can. But I'm also not promising, and we're basically at the mercy of our schedule, which is very, very burdensome, and then the pandemic as well. But I really don't want to try a virtual hearing. I want to do it in person if I at all can. All right?

MR. BLACK: Yes.

THE COURT: So you are doing June -- and say I say that because, Mr. Black, you won this little battle, but you need to be prepared just to move really quickly. I assume anyway you would be the one that has to move to stop

them from going forward in a launch, so you would be prepared -- you would have to prepare yourself for a PI anyway. Correct?

MR. BLACK: Yes, Your Honor. We can do that on papers obviously, and if some testimony is necessary, it's easier to deal with. What we're trying to avoid is if their product is not approved, they've been telling us they're going to get approval forever and they don't have it, and we're going to have a trial. We're talking about two trials on the same patent in October and January. All of their patents are caught up to the January trial.

Obviously, we can do that if it's necessary. We'll be ready to go. We've got the pretrial order done. All of that work is done.

THE COURT: Okay.

MR. BLACK: But you're right. If they get approval --

THE COURT: Yes. [redacted] And I would just say then, the parties need to immediately notify me when they have heard something from the FDA, and then we'll --

MR. BLACK: Thank you, Your Honor.

THE COURT: Yes. That's how we'll just leave it, and hopefully, we're going to hear something by then and

we can move forward. Okay?

So I'm not going to set up a telephone conference, but the parties are both directed to inform me as soon as you hear from the FDA.

MR. BLACK: Thank you, Your Honor.

MR. HALES: Understood, Your Honor. Thank you.

THE COURT: Okay. Anything else I need to address from the plaintiffs?

MR. BLACK: No, Your Honor. Nothing from the plaintiffs.

THE COURT: Anything from the defense?

MR. HALES: No, Your Honor. Thank you.

THE COURT: All right. Thank you, all, and stay safe. We're done. Thanks.

(Telephone conference concluded at 1:53 p.m.)

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EXHIBIT C

REDACTED

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	C.A. No. 18-823-CFC
v.	)	[redacted]
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

LETTER TO THE HONORABLE COLM F. CONNOLLY
FROM BINDU A. PALAPURA, ESQUIRE

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June 24, 2020

VIA ELECTRONIC FILING
The Honorable Colm F. Connolly
United States District Judge
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Unit 31, Room 4124
Wilmington, DE 19801-3555

[redacted]

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC

Dear Judge Connolly:

This firm, together with Kirkland & Ellis LLP, represents Defendant Eagle Pharmaceuticals, Inc. ("Eagle") in the above-captioned matter. We write to apprise the Court of the status of Eagle's Abbreviated New Drug Application ("ANDA") at issue in this litigation, as requested by the Court at the conclusion of the May 18, 2020 Teleconference.

Eagle [redacted]

[redacted]

1 [redacted]

Eagle anticipates having more information [redacted], after it has fully analyzed [redacted]. That said, Eagle does not believe [redacted] will bear on the legal case before your Honor, for which both parties are trial-ready.

Because Eagle may have additional information relating to [redacted] we believe it makes sense for the Court and the parties to talk after Eagle has such information. Eagle will update the Court once it has more information and expects to request the Court to schedule a status conference after that update to discuss the scheduling of trial in this action.

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

BAP:nmt/6776403/45185

cc: Counsel of Record (via electronic mail)

EXHIBIT E

REDACTED

EXHIBIT F

REDACTED

EXHIBIT G

REDACTED

EXHIBIT H

REDACTED

EXHIBIT I

REDACTED